

#### IV. AMENDMENTS TO THE DRAWINGS

--- Replacement and annotated mark-up drawing sheets for amended figures showing the amended figures, if any, are attached at the Appendix hereto. Each figure is in compliance with 37 C.F.R. § 1.84. An explanation of the changes, if any, is set forth below in this "Amendments to the Drawings" section. Replacement drawing sheets are identified in the top margin as "Replacement Sheet." Any replacement drawing sheet including amended figures includes all of the figures appearing on the immediate prior version of the sheet. Any annotated drawing sheets, if the same are required by the Examiner, are identified in the top margin as "Annotated Marked-Up Drawings." Any deleted figure is noted by an instruction to delete the figure. Any corresponding amendment to the specification necessary to be made because of an amendment to the drawings in this section is made in the corresponding "Amendments to Specification" section.

- THE DRAWINGS OF THE PATENT ARE HEREBY AMENDED AS SET FORTH BELOW:

- FIGS. 1A and 2C have been amended to more particularly point out that "10" generally refers to the item depicted. This is in accord with the description of each such figure, and thus it is asserted that such amendments do not introduce new matter. FIGS. 1B and 1C have been redrawn to improve clarity. Again it is asserted that no new matter has been added.

## V. REMARKS/ARGUMENTS

- STATUS OF THE CLAIMS

Before action pursuant to this response, claims 1 - 3, 8 - 20, 35 - 37, and 49 were pending in this application. Claims 4 - 7, 21 - 34, 38 - 48, and 50 - 56 were withdrawn from consideration pursuant to a prior restriction requirements. All pending claims stand rejected pursuant to the Office Action of September 13, 2005. Claims 1, 37 and 49 are canceled herein. Claims 2 - 3, 8 - 20, and 35 - 36 are amended herein. New claims 57 - 61 are added herein.

- OBJECTIONS

- OBJECTIONS TO CLAIMS AND SPECIFICATION

- Examiner's Stance

The Examiner has objected to the drawings "because reference characters '10' and '3' have both been used to designate the implant" (page 2, first paragraph, of the Office Action). The Examiner asserts that "[c]orrected drawing sheets in compliance with 37 CFR 2.121(d) are required" (page 2, first paragraph, of the Office Action). Although the Examiner recites on the "Office Action Summary" page attached to the Office Action that claims 12 - 17 are objected to, no *per se* objections have been raised by the Examiner concerning the claims in the Office Action.

- Applicants' Response

The objections set forth with respect to the drawings are respectfully traversed on the grounds that one of ordinary skill in the art would understand the drawings as depicted. However, as set forth above in the Amendment to Drawings section, FIGS. 1A and 2C have been amended to more particularly point out that "10" generally refers to the item depicted. This is in accord with the description of such figures in the "Detailed Description of Preferred

Embodiments" section, and thus it is asserted that such amendment does not introduce new matter. FIGS. 1B and 1C have been redrawn to improve clarity. Again it is asserted that no new matter has been added. Applicant asserts that such amendments and clarification obviate the Examiner's objections with respect to the drawings.

Applicants asserts that the "Office Action Summary" page is erroneous in characterizing the rejection of claims 12 - 17 under 35 U.S.C. §112 as "objections."

- RESTRICTION REQUIREMENT UNDER 35 U.S.C. §121

- Examiner's Stance

The Examiner asserts that claims 4 - 7, 21 - 34 , 38 - 48 and 50 -56 are withdrawn from further consideration as being drawn to a non-elected invention and species.

- Applicants' Response

Applicants reply below is directed to the claims asserted by the Examiner to be elected.

- REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

- Examiner's Stance

The Examiner has rejected claims 1 - 3, 8 - 20, 35 - 37 and 49 under 35 U.S.C. §112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention" (page 3, paragraph 5, of the Office Action). The Examiner asserts that claim 1 is indefinite in that it provides no "structural nexus between the interface portion and the A support structure," and because "[t]here is no structure defining an 'interface.'" The Examiner asserts that Claim 2 is indefinite in that there is no antecedent support for "central core." The Examiner asserts that "truss-like" in claim 3 is indefinite "for failing to positively limit the same." The Examiner suggests that claim 9 "should recite the implant having a surface defining a bone engaging interface and the interface comprises a plurality of support elements protruding therefrom." In respect of claim 10, the Examiner states that it "is not clear what characteristic is being adapted for fit within a bone canal." The Examiner then asserts that claim 11 is redundant to

claim 9. In respect of claim 12 and 14, the Examiner states there is "no physical nexus between the cable and the support structure." Likewise in regard to Claim 13, the Examiner asserts that there "is no physical nexus between the cable, the bridge element and the support structure." The Examiner asserts that claim 15 is indefinite in that it is "not clear how and by what means asymmetric tension is effected to the cables." The Examiner asserts that claim 16 "should positively recite the cables as having means for adjustment before, during and/or after," and that claim 17 fails to further define the structure of claim 14. In regard to claim 18, the Examiner states that the claim "should recite that the medication is administered after implantation in the bone." In regard to claim 19, the Examiner asserts the claim is indefinite in that "[i]t is not clear if the medication and the coated material are one and the same." The Examiner also finds claim 20 indefinite, but this time for improper alternative language in that "BMP and medication are not equivalent elements." Lastly, the Examiner finds claim 35 indefinite for all of the reasons set forth with respect to claims 1 and 9. The Examiner does not specifically recite the basis of the rejection of claims 36, 37 and 49.

- Applicants' Response

Applicants respectfully traverse the rejection of unamended claims 1 - 3, 8 - 20, 35 - 37 and 49 under 35 U.S.C. §112, second paragraph based in part upon the argument that one of ordinary skill in the art would find such claims to be clear and definite. However, as each of such claims has been amended, or canceled (see claims 1, 37 and 49), herein, as set forth above, the Applicants assert that each of these rejections is mooted.

Applicants have attempted to craft amendments to the claims to overcome each of the Examiner's rejections, in particular taking into mind the need for antecedent support. Claims 2 - 3 and 8 - 20, 36 - 37, now each ultimately depend from independent claim 35. Support for the amendments made is found, among other places, the abstract, page 12 lines 1 - 15, page 19 line 1 - page 20, line 16, page 23, lines 6 - 23, of the specification, and the claims as originally filed, which form part of the specification.

- REJECTIONS UNDER 35 U.S.C. §102(b)

- Examiner's Stance

The Examiner has rejected claims 1, 2, 8 - 11, and 35 - 37 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,231,120 to Day or U.S. Patent No. 4,447,915 to Weber. The Examiner asserts that "[e]ach of Day and Weber disclose an implant comprising an interface portion and central portion wherein the interface portion is deformable upon insertion into a prepared bone canal" (page 5, paragraph 5, of the Office Action).

- Applicants' Response

Applicants respectfully traverse the rejection of claims 1, 2, 8 - 11, and 35 - 37 under 35 U.S.C. §102 (b) based in part on the Examiner's failure to show each of the elements of the unamended claims in the references of record. Applicant notes that the Examiner bears the burden of proof with respect to making out a *prima facie* case of obviousness.

As each of the claims rejected under 35 U.S.C. §102 (b) have been amended or canceled (see, claim 1), Applicants' further arguments are directed to the amended claims.

Each of claims 2, 8 - 11 and 36 - 37 now depend on independent claim 35. Claims 1 and 37 have been canceled and therefore all rejections predicated on these claims are respectfully asserted to be mooted. In respect of independent claim 35, Applicants note no direction by the Examiner to a teaching in either of the references of art of resiliently deformable support elements that are oriented in longitudinal rows. For this reason alone, Applicants assert that claim 35, and through dependency claims 2, 8 - 11, and 36 - 37, cannot be said to be anticipated by the art of record. Applicant notes the failure of the Examiner to show other elements of claim 35 as amended as well. When concentrating on each of the limitations of dependent claims 2, 8 -11, and 36 - 37, Applicants further fail to see how such cited references anticipate the claims.

As anticipation requires that all of the limitations of a claim be found in a single art of record, and as all of such limitations of the present claims are not found in the art of reference, Applicants respectfully assert that each of claims 2, 8 - 11, 35 - 37 cannot be said to be anticipated under 35 U.S.C. §102.

- REJECTIONS UNDER 35 U.S.C. §103(a)

- Examiner's Stance

The Examiner has rejected unamended claims 18 - 20 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,231,120 to Day or U.S. Patent No. 4,447,915 to Weber, as applied to claim 1, and further in view of U.S. Patent No. 4,828,563 to Muller-Lierheim.

The Examiner asserts that "[t]he coating of implant surfaces with growth factors to enhance biocompatibility is taught by Muller-Lieheim ... [and thus] [t]o coat the implant of either of Day or Weber with growth factors for increase tissue compatibility would have been obvious from the teachings of Muller-Lierheim." (page 5, paragraph 8 - page 6, paragraph 1 of the Office Action).

The Examiner has also rejected claims 1, 3 and 49 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,181,930 to Dumbleton *et al.* in view of U.S. Patent No. 4,231,120. The Examiner asserts that "Dumbleton *et al.* discloses an implant comprising an interface and support core [,wherein] [t]he support core comprises a plurality of rods ... [while] Day teaches the use of an implant having an interface formed with deformable elements for better fixation into the prepared bone" (page 6, paragraph 3, of the Office Action). The Examiner asserts that "[t]o form the interface of Dumbleton *et al.* with deformable elements for better fixation to the bone would have been obvious from the teachings of Day" (page 6, paragraph 3, of the Office Action).

- Applicants' Response

Applicants respectfully traverse the rejection of unamended claims 1, 3, 18 - 20 and 49 under 35 U.S.C. §103(a) in part based on the Examiner's use of hindsight reasoning to fabricate each of the elements of the claims, and the failure of the Examiner to provide adequate legally sanctioned motivation for the combination of references cited, in particular the combination of Day or Weber with Muller-Lierheim or Dumbleton *et al.* with Day.

Now, turning to the amended claims in the claim set of 1, 3, 18 - 20 and 49, Applicants assert that all the rejections set forth above with respect to the unamended claims are mooted by cancellation of each of the two independent claims in the claim set, that is, claims 1 and 49. Applicants note that claims 3 and 18 - 20 now ultimately depend on amended claim 35.

In respect of amended claim 35, once more applicant notes no teaching or suggestion in U.S. Patent No. 4,231,120 to Day that implies the use of longitudinally oriented resilient deformable support elements on the interface of the implant. Taking U.S. Patent No. 5,181,930 to Dumbleton *et al.* with U.S. Patent No. 4,231,120 to Day simply does not motivate one to form the structure asserted in amended claim 35.

With respect to U.S. Patent No. 4,828,563 to Muller-Lierheim, Applicants note that the reference does not teach or suggest the hydroxyapatite-based substance of amended claim 19, nor the bone morphogenic medication of amended claim 20, and therefore cannot be said to supply such missing elements to U.S. Patent 4,231,120 to Day or U.S. Patent No. 4,447,915 to Weber. Likewise, the Muller-Lierheim references a surface coating of growth factors "for enhanced compatibility of the implant" (col. 1, lines 60 - 61, of U.S. Patent No. 4,828,563 to Muller-Lierheim) not a medication as set forth in claim 18 which one skilled in the art would understand is a substance for the treatment of a physical malady.

- ALLOWABLE SUBJECT MATTER
- Examiner's Stance

The Examiner has asserted that claims 12 - 17 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. §112, second paragraph and to include all of the limitations of the base claim and any intervening claims.

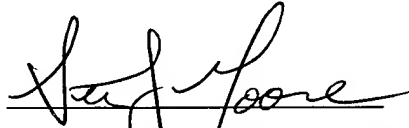
- Applicants' Response

Applicants extend their appreciation to the Examiner for the indication of the allowance of such claims. Applicants assert that new claims 57 - 61, which parallel unamended claims 12 - 17, and which are drafted to respond to the Examiner's rejections of claims 12 - 17, should be allowable in light of the Examiner's stance.

CONCLUSION TO REMARKS

Applicants assert that this response is fully responsive to the Examiner's office action dated September 13, 2005. Applicants respectfully seek early allowance of the pending claims.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Steven J. Moore", written over a horizontal line.

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## **VI. APPENDIX**

- *Attached hereto are 2 Replacement Sheets (for pages 25 and 26 of this Response) directed to FIGS. 1A - 1C, and FIG. 2C.*